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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,756

12/21/2005

Richard E Musty

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,756	Applicant(s) MUSTY ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/5/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Reconsideration

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/2008 has been entered.

Response to Arguments

Applicant's arguments have been fully considered. In particular, Applicants argue that the finality of the previous rejection should be withdrawn because they feel that the claim amendments did not provoke the modification of the rejection.

In response to the above arguments, and as was noted in the Advisory Action, the original claims were drawn to a pharmaceutical composition (claims 1-11) and a method of using the pharmaceutical composition (claims 14-15 and 18-19). It is noted that the original rejection was applied using Travis as the primary reference due to the teachings of the pharmaceutical composition; however, Applicants amended the claims and cancelled the claims drawn to the pharmaceutical composition and the rejection was modified in an effort to better address the method of use of the composition. It is also noted that the combination of references was modified, but the same references

were used, again in an effort to better address the method claims since the composition claims were cancelled. Therefore, the finality of the final office action is maintained.

Applicants argue over the 35 USC 103 rejection that Brooke provides no specific disclosure of the use of cannabichromene for any given medical indication and does not provide a written description of the use of cannabichromene in the treatment of mood disorders. Further, Applicants assert that the combination of Brooke et al with Travis and Turner et al. is incorrect because Brooke states that the medical uses of cannabis include a variety of disease but does not teach that cannabichromene is useful for treating the diseases listed in Col. 1.

In response to the above argument, Brooke et al. teaches that several medicinal uses have been found for the active ingredients of cannabis, of which includes cannabichromene. Brooke et al. further teaches that the medicinal uses of cannabis include stress and depression (see Col. 1, lines 24-33). Brooke et al. teaches other disorders in which it is well known in the art that cannabis and its active ingredients are useful for treating, including nausea and pain associated with cancer and chemotherapy and AIDS. Therefore, it would be obvious to a person of ordinary skill in the art that active ingredients of cannabis are a useful treatment for a variety of disorders, which include mood disorders such as stress and/or depression.

Applicants have also argued that mature plants contain very little cannabichromene (CBC) and provide articles to back up this argument (Vogelmann et al., Rowan & Fairbairn). Applicants contend that one would interpret that the medicinal

uses of cannabis would not include CBC as a candidate compound to try for any medicinal indication.

It is noted that the articles teach that there are amounts, sometimes large amounts, of CBC contained in mature plants. In particular, Rowan & Fairbairn teach that THC-rich race always possesses CBC sometimes in large amounts. Also, Vogelmann et al. teaches that in some light situations there is a higher concentration of CBC compared to THC and CBG. Accordingly, there is no reason to expect that CBC would not have any medicinal purpose.

Accordingly, the rejection is deemed proper and is maintained. Please see below.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15, 18-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,51) and Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Brooke et al. teach that medicinal uses, such as depression, have been found for the active ingredients of cannabis, including cannabichromenes (meeting the limitation of claims 14-15; Col. 1, lines 23-33).

Brooke et al. does not teach a cannabichromene compound of the same structural formula as Formula (I) in claims 14 and 20-24, that the cannabichromene compound is an extract of at least one cannabis plant as claimed in claims 18 and 25-27 or the route of administration.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds of the general formula (I), wherein R^1 is OH, R^2 is H, R^3 is a C_{5-12} alkyl, Q is O, R^6 is C_{1-6} alkyl, and R^{12} and $R^{12'}$ are C_{1-6} alkyl (meeting the limitations of claims 1 and 20-24; Col. 2, lines 21, 25, 55-56; Col. 3, lines 24, 35, 39, 64; Col. 4, line 2). The compositions are further obvious over general formula (I) when R^3 is C_3H_7 of claims 20-21 because the difference between C_3H_7 and C_5H_{11} (as taught by Travis) differ in only two carbons and are considered analogous over each other. Travis further teaches that the alkyl groups of R_3 can be straight chained (meeting the limitations of claim 22; paragraph 0102). Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with

cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression. It would have further been obvious to use the cannabichromene composition taught by Travis and Turner et al. to treat depression, because Travis and Turner et al. teach cannabichromene compositions that are useful as pharmaceutical compositions. One would have been motivated to use the cannabichromene compositions taught by Travis and Turner et al. to treat depression with a reasonable expectation of success because Brooke et al. teaches that cannabichromenes show medicinal use in treating depression.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617